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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/939,161	08/24/2001	Richard W. Voellmy		4118
7590 05/06/2004			EXAMINER	
Richard W. Voellmy			OH, SIMON J	
Dept. of Biochemistry & Molecular Biology University of Miami School of Medicine			ART UNIT	PAPER NUMBER
1011 N.W. 15th Street Miami, FL 33136			1615	
			DATE MAILED: 05/06/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	09/939,161	VOELLMY, RICHARD W.
Office Action Summary	Examiner	Art Unit
	Simon J. Oh	1615
The MAILING DATE of this communication Period for Reply	n appears on the cover sheet w	ith the correspondence address
A SHORTENED STATUTORY PERIOD FOR R THE MAILING DATE OF THIS COMMUNICATI  - Extensions of time may be available under the provisions of 37 C after SIX (6) MONTHS from the mailing date of this communicatic  - If the period for reply specified above is less than thirty (30) days, - If NO period for reply is specified above, the maximum statutory p  - Failure to reply within the set or extended period for reply will, by Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	ON. FR 1.136(a). In no event, however, may a on. a reply within the statutory minimum of thin period will apply and will expire SIX (6) MOI statute, cause the application to become A	reply be timely filed ty (30) days will be considered timely. NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed on	20 January 2004.	
2a)⊠ This action is <b>FINAL</b> . 2b)□	This action is non-final.	
3) Since this application is in condition for all closed in accordance with the practice un	· · · · · · · · · · · · · · · · · · ·	•
Disposition of Claims		
4) ⊠ Claim(s) 1-22 is/are pending in the application 4a) Of the above claim(s) is/are with 5) ☐ Claim(s) is/are allowed.  6) ⊠ Claim(s) 1-22 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction as	hdrawn from consideration.	
Application Papers		
9)☐ The specification is objected to by the Exa	miner.	
10) The drawing(s) filed on is/are: a)	] accepted or b)☐ objected to	by the Examiner.
Applicant may not request that any objection to	o the drawing(s) be held in abeya	nce. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the control of the control	· · · · · · · · · · · · · · · · · · ·	
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for for a) All b) Some * c) None of:  1. Certified copies of the priority docur 2. Certified copies of the priority docur 3. Copies of the certified copies of the application from the International But * See the attached detailed Office action for a	ments have been received. ments have been received in A priority documents have beer ureau (PCT Rule 17.2(a)).	Application No  received in this National Stage
Attachment(s)		
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-94</li> </ol>		Summary (PTO-413) s)/Mail Date
Notice of Braitsperson's Patent Brawing Review (PTO-94     Information Disclosure Statement(s) (PTO-1449 or PTO/S Paper No(s)/Mail Date		nformal Patent Application (PTO-152)

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#### **DETAILED ACTION**

## Papers Received

Receipt is acknowledged of the applicant's response and petition for extension of time, both received on 20 January 2004.

## Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-15, 21, and 22 under 35 U.S.C. 112, first paragraph, for lack of enablement, is maintained.

## Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li *et al.* in view of Jimenez *et al.* is maintained.

### Response to Arguments

Applicant's arguments filed 20 January 2004 have been fully considered but they are not persuasive. Once again, the applicant's arguments appear to be based upon a narrow interpretation of both the claims and the prior art. For purposes of examination, the prior art is

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considered valid and is considered in its entirety for all that it contains. It is the position of the examiner that the prior art disclosures relied upon to make the prior art rejection of record are fairly taught by the applied references. See MPEP § 2111 and 2123. Furthermore, the motivation to combine references under 35 U.S.C. 103 is not strictly required to come from within the prior art references themselves. See MPEP § 2142. Finally, issued patents are presumed to be valid. See 35 U.S.C. 282. Should the applicant seek to contest this validity, he is advised to seek action through the courts.

Regarding the maintained rejection under 35 U.S.C. 112, the examiner has evaluated the specification, including the examples, and has found several deficiencies:

- There is a limited amount of data on the instantly claimed methods, which is insufficient to support such a broad concept within the claims.
- There is a limited selection of chemotherapy drugs being applied, the dosages of which are not clearly correlated to the induction of alopecia
- There are limited embodiments of protective formulations being applied, such as liposomal formulations.

In view of this, it is the position of the examiner that the claims do not clearly reflect the scope of what has been described within the examples. The rejection under 35 U.S.C. 112 is deemed proper and is maintained.

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#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

## Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh Examiner Art Unit 1615

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